Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Performance in Initiating Clinical Research - Quarter 3 (2014/15)

All clinical trials granted NHS Permission between 01 January 2014 - 31 December 2014

Trust Reference Code	Research Ethics Committee Reference Number	Name of Trial	Date of NHS Permission	Date of Receipt of Valid Research Application (VRA)	First Patient Recruited?	Date of First Patient Recruited	Calendar Days between VRA and First Patient	Benchmark Met?	Reason for Delay
C&W14/111	10/H1107/70	Is a short course of azithromycin effective in the treatment of mild to moderate pelvic inflammatory disease (PID)?	26/11/2014	20/11/2014	No	Pending	Not applicable	Pending	Deadline is 29 January 2015.
C&W12/074	12/NW/0214	TAILoR - (TelmisArtan and InsuLin Resistance in HIV): A Dose-Ranging Phase II Randomised Open-Labelled Trial of Telmisartan as a strategy for the Reduction of Insulin Resistance in HIV-Positive Individuals on Combination Antiretroviral Therapy (cART)	12/05/2014	12/05/2014	Yes	20/06/2014	39	Yes	
C&W14/069	12/SC/0014	Vasopressin vs Noradrenaline as Initial therapy in Septic Shock (VANISH)	15/07/2014	07/07/2014	No	Pending	Not applicable	No	**Source of delays: Sponsor** D - Delays caused by sponsor: sponsor refused to grant green light for recruitment following NHS Permission because of revised training requirements put in place by sponsor. Green light for recruitment received on 02/09/2014, which was 57 days following VRA. F - No eligible patients seen during the reporting period: patients sought but no eligible patients identified, despite 6 potential patients being screened.
C&W13/085	13/EE/0270	A Global Registry to Evaluate Long-Term Effectiveness of Neurostimulation Therapy for Pain	04/07/2014	30/06/2014	Yes	15/07/2014	15	Yes	
C&W13/094	13/EM/0154	A multi-centre randomised controlled trial evaluating cast treatment versus surgical fixation on wrist function for fractures of the scaphoid waist in adults	13/01/2014	13/01/2014	No	Pending	Not applicable	No	**Source of delays: Both Sppnsor and NHS** D - Delays caused by sponsor: protocol amendments implemented by sponsor organisation meant that recruitment packs were not received by site within 70 day period. E - Staff availability issues at site: Following 70 day period, staff changes in the clinical team affected ability to run study. Performance management plan now implemented between Trust and sponsor with a review date of 06/10/2014. Outcome of review has been withdrawal of NHS Permission following consultation with clinical team and sponsor.
C&W14/004	13/LO/0147	A phase IV study to determine the oral and genital tract concentration of Maraviroc required for ex vivo protection from HIV-1 using Maraviroc 300mg stat	10/03/2014	04/03/2014	Yes	10/06/2014	98	No	**Source of delays: Sponsor** D - Delays caused by sponsor: sponsor refused to grant green light for recruitment following NHS Permission because of a protcol amendment regarding exclusion criteria for heptatus A screening (despite original unamended protocol having regulatory approvals). Regulatory approvals for this amendment were received 09/05/2014 (REC) and 15/05/2014 (MHRA). Following receipt of these approvals, site was able to begin recruit. First patient was recruited 26 days following MHRA approval.
C&W13/100	13/LO/1908	Evaluating the nutritional adequacy of a diet low in fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP's) in children with functional gastrointestinal disorders	17/02/2014	13/02/2014	Yes	28/04/2014	74	No	**Source of delays: Neither Sponsor nor NHS** G - Eligible patients seen during the relevant period but did not consent to participate in the trial - 2 were given info prior to deadline but due to Easter were unable to be scheduled in in time. The fault therefore lies neither with the NHS Provider nor sponsor - patients would have consented if the public holiday fell on a different date.
C&W14/022	13/SC/0436	ASAP - Early low dose steroids for adults admitted to hospital with influenza-like illness during a pandemic: a randomised placebo controlled trial	18/06/2014	18/06/2014	No	Pending	Not applicable	Not applicable	**Source of delays: Neither Sponsor nor NHS** J - Other: study will sit in hibernation stage until C&W is activated as a research site in the event of a pandemic flu episode. Site will only be activated by sponsor, and therefore become open to recruitment, when a pandemic flu event is declared.
C&W14/029	13/WM/0017	select-d: Anticoagulation Therapy in SELECTeD Cancer Patients at Risk of Recurrence of Venous Thromboembolism	07/07/2014	07/07/2014	Yes	08/08/2014	32	Yes	
C&W13/090	14/EE/0048	A comparison between thermal imaging (thermography) and laser doppler imaging for the assessment of adult burns injuries	23/01/2014	17/01/2014	Yes	05/03/2014	47	Yes	
C&W14/025	14/EE/0188	The effects of electronic cigarettes on the microcirculation of the hand	31/07/2014	31/07/2014	Yes	25/08/2014	25	Yes	
C&W14/046	14/EE/1027	The Chelsea Critical Care Physical Assessment Tool (CPAx): Validation and Evaluation of a score to grade physical recovery from critical illness.	08/09/2014	21/08/2014	Yes	18/09/2014	28	Yes	
C&W14/079	14/EE/1063	A Phase III, Open Label, Randomized Study of AZD9291 versus Platinum-Based Doublet Chemotherapy for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer whose Disease has Progressed with Previous Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and whose Tumours harbour a T790M mutation within the Epidermal Growth Factor Receptor Gene	18/09/2014	18/09/2014	Yes	01/10/2014	13	Yes	
C&W14/002	14/LO/0083	An open label study examining the efficacy and cardiovascular risk of immediate versus deferred switch from a boosted PI to dolutegravir (DTG) in HIV infected patients with stable virological suppression	08/04/2014	08/04/2014	Yes	02/05/2014	24	Yes	
C&W14/063	14/LO/0667	A Phase III Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Treatment-Naive Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are Co-Infected with HIV	12/06/2014	09/06/2014	Yes	13/06/2014	4	Yes	
C&W14/066	14/LO/0803	Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Pharmacodynamics, Safety and Pharmacokinetics of BMS-955176 (Double-Blinded) and BMS-955176 with Atazanavir +/- Ritonavir (Open-Labeled) in HIV-1 Infected Subjects	14/07/2014	11/07/2014	Yes	29/07/2014	18	Yes	
C&W14/087	14/LO/1227	Pharmacokinetics of DOLUTEGRAVIR once daily and ELVITEGRAVIR/COBICISTAT once daily over 10 days following drug intake cessation in healthy volunteers	19/08/2014	19/08/2014	Yes	21/08/2014	2	Yes	
C&W14/098	14/LO/1381	A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Each in Combination With TRUVADA™, in Treatment-Naïve HIV-1 Infected Subjects	05/11/2014	04/11/2014	Yes	25/11/2014	21	Yes	
C&W14/107	14/LO/1493	A phase IV open-label, multi-centre, randomised, dual-arm, pilot study to assess the feasibility of switching individuals receiving Efavirenz with continuing Central Nervous System (CNS) toxicity to Dolutegravir	19/12/2014	19/12/2014	No	Pending	Not applicable	Pending	Deadline is 27 February 2015.
C&W14/092	14/LO/1513	A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/ Tenofovir DF or Efavirenz/ Emtricitabine/ Tenofovir DF) compared to Ritonavir boosted Atazanavir plus Abacavir/ Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR =70 mL/min	27/10/2014	14/10/2014	Yes	15/12/2014	62	Yes	
C&W14/062	14/SC/0225	A Phase 3, Randomized, Double-Blind, Switch Study to Evaluate F/TAF in HIV 1 Positive Subjects who are Virologically Suppressed on Regimens containing FTC/TDF	12/06/2014	06/06/2014	Yes	30/06/2014	24	Yes	
C&W14/024	14/WM/1047	Trial of Improvisational Music Therapy's Effectiveness for Children with Autism (TIME-A): UK Arm of the TIME-A Study.	23/09/2014	22/09/2014	Yes	04/11/2014	43	Yes	